

Appl. No. 09/12,725
Response dated October 6, 2003
Reply to Office action of June 6, 2003

REMARKS/ARGUMENTS

Claims 3, 4, 6, 7 and 27 are pending in the application. Claims 6 and 27 were rejected under 35 U.S.C. 102(b) as being anticipated by JP 4356156A. The applicant respectfully traverses this rejection and submits that JP 4356156A does not teach, disclose, suggest or make inherent the process of eliminating pathogenic bacteria in raw oysters (Claim 6) or raw molluscan shellfish (Claim 27) by exposing raw oysters (molluscan shellfish) to hydrostatic pressure of between 20,000 p.s.i. and 80,000 p.s.i. for 1 – 15 minutes at ambient temperature, without causing thermal and mechanical damage to the raw oysters or the raw molluscan shellfish.

JP 4356156 teaches a process of opening shells of raw oysters by subjecting the raw oysters to hydrostatic pressure of 14,615 – 44,087 p.s.i. for 0.5 – 10 minutes at ambient temperature. The cited reference is silent on a possibility or desirability of the process being conducted at 20,000 p.s.i. or at pressures above 44,087 p.s.i. The cited reference is silent on what possible effect different pressure ranges would have on raw oysters. More importantly the cited reference is silent on the issue of pathogenic bacteria elimination. Therefore, the inventor of the cited reference did not recognize a possibility of the hydrostatic pressure being used for treating bacterial contamination in oysters.

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Under principles of inherency, when a reference is silent about an asserted inherent characteristic, **it must be clear that the missing descriptive matter is necessarily present in the thing described in the reference**, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

Examiner relied on a single page, page 203, heading 1.2 of Cheftel [Effects of high hydrostatic pressure on food constituents: an overview] suggesting that it was known that high pressure treatment of seafood destroyed pathogenic organisms such as *Vibrio*. Examiner's reliance on Cheftel is misplaced. Cheftel did not provide evidence that "high pressure treatment of seafood destroyed pathogenic organisms." Instead, Cheftel tentatively theorized that this result could be achieved by using high pressure.

As the court stated in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981)(quoting *Hansgird v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)):

"Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient".

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In this case, it is not clear that the missing descriptive matter (i.e., that high pressure in the range of 20,000 p.s.i. to 80,000 p.s.i. eliminates pathogenic bacteria) is necessarily present in the description of JP 4356156 or Cheftel, and that it would be so recognized by persons of ordinary skill.”

The applicant encloses four Declarations under Section 132 Exhibits 1 – 4) from persons having more than ordinary skill in the art. One of the declarants is Mr. Le Roy Chauvin, who has been working in the oyster industry since 1953, who is an active member of North American Oyster Institute and whose recommendations are followed and enforced by the Federal Food and Drug Administration.

The second declarant is Mr. Michael C. Voisin, who has been working in the field of seafood processing since 1971, who is President and Chairman of the Board of Louisiana Oyster Dealers and Growers Association, active member of Gulf and South Atlantic Fisheries Development Foundation, Interstate Shellfish Sanitation Conference and several other organizations that deal with seafood processing and seafood safety on the National and State level.

The third declarant is Mr. Alfred R. Sunseri who has been working in the oyster processing and distributing industry since 1980, who is an active member of the Louisiana Oyster dealers and growers Association, Louisiana Oyster Task Force, Gulf Oyster Industry Council and the Interstate Shellfish Sanitation Conference.

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The fourth declarant is Mr. Christopher Lee Nelson who has been working in the oyster industry since 1989, who is an active member of the National Fisheries Institute, Molluscan Shellfish Institute, National Shellfisheries Association, Southeastern Fisheries Association and several other organizations that deal with the problems facing the seafood industry.

All declarants examined the instant application, its prosecution file history, JP 4356156, Cheftel and Tesvich (that is all cited references). All declarants recognize that the cited reference of JP 4356156 is silent on the effects of high pressure processing in the range of 14,615 – 44,087 p.s.i. for 0.5 – 10 minutes at ambient temperature on elimination of Vibriones. Having then reviewed Cheftel, the declarants reached a conclusion that it would not have occurred to them “to read the Japanese application or Cheftel’s page, singularly or in combination, as a guiding manual or even a suggestion for elimination of *Vibrio Vulnificus* in molluscan shellfish.” All declarants stated that it “is not inherent in the Japanese reference and is not recognized inherent by” them, based on their “experience and knowledge of seafood processing, that the method steps of the Japanese application would result in elimination of bacteria in molluscan shellfish.” The declarants further stated that they “have reached the same conclusion after considering the Cheftel’s paper.”

The declarants also disagreed with the examiner's statement that a person of ordinary skill in the art would have expected the same result (Vibrio elimination) after having read the Japanese reference. In their opinion, "Japanese application addresses only one subject - oyster shucking. There is nothing in that paper that have told" them "or suggested to" them, "or made inherent to" them "that using certain pressures and time values can eliminate Vibrio in seafood without changing the taste of seafood."

Therefore, prima facie case of anticipation of Claims 6 and 27 has not been established.

Claims 3, 4 and 7 were rejected under 35 U.S.C. 103(a) as being unpatentable over JP 4356156 in view of Tesvich et al (5,773,064).

The applicant respectfully traverses this rejection. Tesvich et al was cited for two propositions – that keeping uncooked food at refrigeration temperatures is a common method of preservation and that bands keep shells from opening during processing.

As stated above, the primary reference is silent on the issue of elimination of pathogenic bacteria in seafood by exposing the seafood to high hydrostatic pressure in the range of 20,000 p.s.i. and 80,000 p.s.i. for 1 – 15 minutes at ambient temperature, without causing thermal and mechanical damage to the raw oysters or the raw molluscan shellfish, while retaining sensory characteristics of said raw molluscan shellfish.

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The declarations of Messrs. Nelson, Sunseri, Chauvin and Voisin address the issue of obviousness as well.

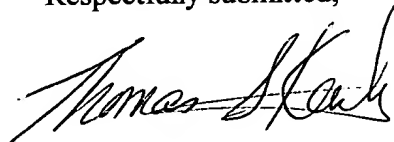
The declarants reviewed the patent of Tesvich and Japanese application as they relate to Claims 3, 4 and 7 and state that they disagreed with the examiner in his assessment of the differences between Claims 3, 4, and 7 of Mr. Voisin's application and the combined disclosure of the Japanese application and Tesvich's patent. The declarants believe "that it would not have been obvious to a person familiar with seafood industry to pressurize seafood at 20,000 p.s.i. and 80,000 p.s.i., without application of heat, without causing damage to shellfish, for a period of time of between 1 and 15 minutes in order to destroy bacteria in raw molluscan shellfish after having reviewed JP 4356156A and Tesvich. The mere fact that Tesvich suggests banding and refrigeration of seafood after "mild heat treatment" does not change the result – neither JP 4356156A nor Tesvich, singularly or combined together, suggest, make inherent or obvious what Mr. Voisin's claims 3, 4, and 7 teach."

Since the prior art failed to teach elimination of pathogenic bacteria, failed to teach pressurization of shellfish at 20,000 – 80,000 p.s.i. at ambient temperature while retaining sensory characteristics of raw shellfish, since persons of ordinary skill in the art did not find Claims 3, 4, and 7 obvious in light of the teachings of the cited prior art, prima facie case of obviousness of Claims 3, 4 and 7 has not been established.

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In view of the above, reconsideration of rejection of the claims under 35 U.S.C.
102 and 103 and allowance thereof is respectfully requested.

Respectfully submitted,



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Attorney for Applicant

<p>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to: Assistant Commissioner for Patents Post Office Box 1450 Alexandria, VA 22313-1450</p> <p>On: 10-6-03 By: <u>Pamela Gautreaux</u> Pamela Gautreaux</p>
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ernest A. Voisin

Serial No.: 09/121,725

Examiner Drew Becker

Filed: July 24, 1998

Group Art Unit 1761

For: A Process of Elimination of Bacteria in
Shellfish, of Shucking Shellfish and
an Apparatus Therefor

DECLARATION

I, Le Roy Chauvin, declare and say:

That I am a citizen of the United States of America and I reside at 7614 Main Street, Apt. 205, Houma, Louisiana 70360. I began my work in the oyster industry in 1953 and have worked in this field ever since.

That I have almost fifty years of experience in all aspects of oyster treatment, from cultivating oysters to harvesting, processing, distribution, canning, freezing and breeding. I was the first person to ship shell oysters to the Chesapeake Bay area of Virginia, Maryland, New Jersey and the Florida coast.

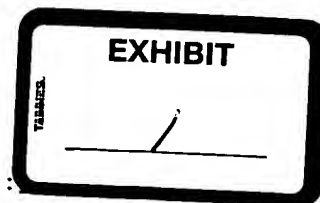
That I am a member of North American Oyster Institute, that my recommendations relating to improving fresh shell oyster quality are being followed and enforced by the Federal Food and Drug Administration to this day.

That I made numerous improvements in the field of growing oysters off bottom from a hatchery. I am a patentee of U.S. patent No. 5,579,724 issued December 3, 1996. That I teach students how to grow oysters started in a hatchery off bottom. I am currently writing a textbook on this subject.

I am intimately familiar with the problems faced by seafood industry and technical solutions offered by numerous individuals and companies.

I am aware that the industry has been actively engaged in finding solution to the problem of seafood contamination by naturally-occurring marine bacteria, such as *Vibrio Vulnificus* and others.

I have reviewed the above-identified application of Mr. Ernest A. Voisin, the prosecution history of the application, Japanese application identified as JP 4356156A, Chefel [Effects on high hydrostatic pressure on food constituents: an overview] (page 203, heading 1.2), and patent No. 5,773,064 (Tesvich).



Having reviewed the Office Action of Examiner Becker dated June 6, 2003 and having considered statements made by the examiner, I submit that I disagree with the examiner in his assessment of the Japanese application as it is applied to claims 6 and 27. It is my belief that the Japanese reference does not teach a person familiar with the seafood industry how to solve the problem of bacterial contamination. The fact that the Japanese inventor suggests exposing oysters to hydrostatic pressures of 14,615 – 44,087 p.s.i. for 0.5 – 10 minutes at ambient temperatures for the purpose of opening oysters does not translate, suggest, imply or make inherent the teachings of Claims 6 and 27 of Mr. Voisin's application.

I have also reviewed Cheftel's reference and disagree with examiner's assessment of the application of that reference to a real-life problem. Cheftel, while theorizing on the possibility of using high pressure in treating cheeses, minced meat and other food products (note the words "provisional and tentative" at the top of the page) also suggests using high pressure in gelation of muscle protein (paragraph 2.1). To me it suggests that Cheftel did not appreciate the danger of indiscriminately using high pressure in oysters and other delicate seafood items if one does not wish to cause irreversible damage of the product. Therefore, it would not have occurred to me to read the Japanese application or Cheftel's page, singularly or in combination, as a guiding manual or even a suggestion for elimination of *Vibrio Vulnificus* in molluscan shellfish. I submit that it is not inherent in the Japanese reference and is not recognized inherent by me, based on my experience and knowledge of seafood processing, that the method steps of the Japanese application would result in elimination of bacteria in molluscan shellfish. I have reached the same conclusion after considering the Cheftel's page.

I also disagree with the examiner's statement that a person of ordinary skill in the art would have expected the same result (*Vibrio* elimination) after having read the Japanese reference. It is my opinion that Japanese application addresses only one subject - oyster shucking. There is nothing in that paper that have told me or suggested to me, or made inherent to me that using certain pressures and time values can eliminate *Vibrio* in seafood without changing the taste of seafood.

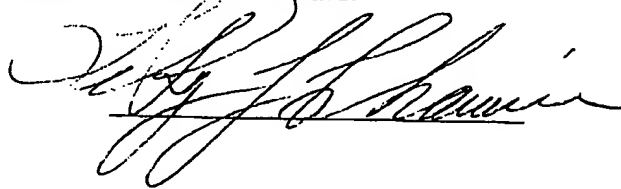
I have further reviewed the patent of Tesvich and Japanese application as they relate to Claims 3, 4 and 7. I disagree with the examiner in his assessment of the differences between Claims 3, 4, and 7 of Mr. Voisin's application and the combined disclosure of the Japanese application and Tesvich's patent. It is my belief that it would not have been obvious to a person familiar with seafood industry to pressurize seafood at 20,000 p.s.i. and 80,000 p.s.i., without application of heat, without causing damage to shellfish, for a period of time of between 1 and 15 minutes in order to destroy bacteria in raw molluscan shellfish after having reviewed JP 4356156A and Tesvich. The mere fact that Tesvich suggests banding and refrigeration of seafood after "mild heat treatment" does not change the result - neither JP 4356156A nor Tesvich, singularly or combined together, suggest, make inherent or obvious what Mr. Voisin's claims 3, 4, and 7 teach.

I submit that Mr. Voisin's invention is unique and novel in the industry; it provided a viable solution to a long-existing problem. Mr. Voisin achieved success where many

others before him failed. It is for this reason that this inventor received acclaim from other seafood processors, who gave him "Processor of the Year" award.
Further declarant saeyth not.

Date:

Oct 1, 2003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ernest A. Voisin

Serial No.: 09/121,725

Examiner Drew Becker

Filed: July 24, 1998

Group Art Unit 1761

For: A Process of Elimination of Bacteria in
Shellfish, of Shucking Shellfish and
an Apparatus Therefor

DECLARATION

I, Michael C. Voisin, declare and say:

That I am a citizen of the United States of America and I reside at 116 East Ellendale Est. Drive, Houma, Louisiana 70360.

That I attended Nicholls State University in Thibodaux, Louisiana in 1973, 1974, and 1976.

That since 1971 I have been working in the field of seafood processing. I have been employed by Motivati Seafoods, Inc. of Houma, Louisiana since 1971. I have firsthand knowledge and experience in all aspects of seafood processing, including farming, harvesting, plant processing and distribution. Since about August 1971, I have been General Manager of Motivati Seafoods, Inc., a corporation engaged in seafood processing. I am an active member of Louisiana Oyster Dealers & Growers Association; I was President of this organization and Chairman of the Board. I am also an active member of Gulf and South Atlantic Fisheries Development Foundation; I was President of this organization and Board of Trustees member.

That I am an active member of Interstate Shellfish Sanitation Conference, Terrebonne Parish Economic Development Consortium, Louisiana Restaurant Association, Southeastern Fisheries Association, Louisiana Seafood Processors Council, Gulf Oyster Industry Council, National Fisheries Institute and Molluscan Shellfish Institute of North America. In many of the listed organizations I served as President, Board member and Chairman.

That I was also appointed to serve on National Shellfish Pollution Indicator Program, National Fish and Seafood Promotion Council, and many others. A more detailed Resume is attached herewith.

I am intimately familiar with the problems faced by seafood industry and technical solutions offered by numerous individuals and companies.

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I am aware that the industry has been actively engaged in finding solution to the problem of seafood contamination by naturally-occurring marine bacteria, such as *Vibrio Vulnificus* and others.

I have reviewed the above-identified application of Mr. Ernest A. Voisin, the prosecution history of the application, Japanese application identified as JP 4356156A, Cheftel [Effects on high hydrostatic pressure on food constituents: an overview] (page 203, heading 1.2), and patent No. 5,773,064 (Tesvich).

Having reviewed the Office Action of Examiner Becker dated June 6, 2003 and having considered statements made by the examiner, I submit that I disagree with the examiner in his assessment of the Japanese application as it is applied to claims 6 and 27. It is my belief that the Japanese reference does not teach a person familiar with the seafood industry how to solve the problem of bacterial contamination. The fact that the Japanese inventor suggests exposing oysters to hydrostatic pressures of 14,615 – 44,087 p.s.i. for 0.5 – 10 minutes at ambient temperatures for the purpose of opening oysters does not translate, suggest, imply or make inherent the teachings of Claims 6 and 27 of Mr. Voisin's application.

I have also reviewed Cheftel's reference and disagree with examiner's assessment of the application of that reference to a real-life problem. Cheftel, while theorizing on the possibility of using high pressure in treating cheeses, minced meat and other food products (note the words "provisional and tentative" at the top of the page) also suggests using high pressure in gelation of muscle protein (paragraph 2.1). To me it suggests that Cheftel did not appreciate the danger of indiscriminately using high pressure in oysters and other delicate seafood items if one does not wish to cause irreversible damage of the product. Therefore, it would not have occurred to me to read the Japanese application or Cheftel's page, singularly or in combination, as a guiding manual or even a suggestion for elimination of *Vibrio Vulnificus* in molluscan shellfish. I submit that it is not inherent in the Japanese reference and is not recognized inherent by me, based on my experience and knowledge of seafood processing, that the method steps of the Japanese application would result in elimination of bacteria in molluscan shellfish. I have reached the same conclusion after considering the Cheftel's page.

I also disagree with the examiner's statement that a person of ordinary skill in the art would have expected the same result (*Vibrio* elimination) after having read the Japanese reference. It is my opinion that Japanese application addresses only one subject - oyster shucking. There is nothing in that paper that have told me or suggested to me, or made inherent to me that using certain pressures and time values can eliminate *Vibrio* in seafood without changing the taste of seafood.

I have further reviewed the patent of Tesvich and Japanese application as they relate to Claims 3, 4 and 7. I disagree with the examiner in his assessment of the differences between Claims 3, 4, and 7 of Mr. Voisin's application and the combined disclosure of the Japanese application and Tesvich's patent. It is my belief that it would not have been obvious to a person familiar with seafood industry to pressurize seafood at 20,000 p.s.i.

and 80,000 p.s.i., without application of heat, without causing damage to shellfish, for a period of time of between 1 and 15 minutes in order to destroy bacteria in raw molluscan shellfish after having reviewed JP 4356156A and Tesvich. The mere fact that Tesvich suggests banding and refrigeration of seafood after "mild heat treatment" does not change the result - neither JP 4356156A nor Tesvich, singularly or combined together, suggest, make inherent or obvious what Mr. Voisin's claims 3, 4, and 7 teach.

I submit that Mr. Voisin's invention is unique and novel in the industry; it provided a viable solution to a long-existing problem. Mr. Voisin achieved success where many others before him failed. It is for this reason that this inventor received acclaim from other seafood processors, who gave him "Processor of the Year" award.
Further declarant saeyth not.

Date:

10/1/03

Mark Voisin



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ernest A. Voisin

Serial No.: 09/121,725

Examiner Drew Becker

Filed: July 24, 1998

Group Art Unit 1761

For: A Process of Elimination of Bacteria in
Shellfish, of Shucking Shellfish and
an Apparatus Therefor

DECLARATION

I, Alfred R. Sunseri, declare and say:

That I am a citizen of the United States of America and I reside at 833 Celeste Avenue, River Ridge, LA 70123. I began my work in the oyster processing and distributing industry in 1980 and have been active in this field ever since. I am totally experienced with oyster processing, distributing, farming, as well as, state and national regulations and requirements for oyster processing and distribution.

I am an active member of the Louisiana Oyster Dealers and Growers Association, Louisiana Oyster Task Force, Gulf Oyster Industry Council, and the Interstate Shellfish Sanitation Conference.

I am intimately familiar with the problems faced by seafood industry and technical solutions offered by numerous individuals and companies.

I am aware that the industry has been actively engaged in finding solution to the problem of seafood contamination by naturally-occurring marine bacteria, such as *Vibrio Vulnificus* and others.

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EXHIBIT

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does not translate, suggest, imply or make inherent the teachings of Claims 6 and 27 of Mr. Voisin's application.

I have also reviewed Cheftel's reference and disagree with examiner's assessment of the application of that reference to a real-life problem. Cheftel, while theorizing on the possibility of using high pressure in treating cheeses, minced meat and other food products (note the words "provisional and tentative" at the top of the page) also suggests using high pressure in gelation of muscle protein (paragraph 2.1). To me it suggests that Cheftel did not appreciate the danger of indiscriminately using high pressure in oysters and other delicate seafood items if one does not wish to cause irreversible damage of the product. Therefore, it would not have occurred to me to read the Japanese application or Cheftel's page, singularly or in combination, as a guiding manual or even a suggestion for elimination of *Vibrio Vulnificus* in molluscan shellfish. I submit that it is not inherent in the Japanese reference and is not recognized inherent by me, based on my experience and knowledge of seafood processing, that the method steps of the Japanese application would result in elimination of bacteria in molluscan shellfish. I have reached the same conclusion after considering the Cheftel's page.

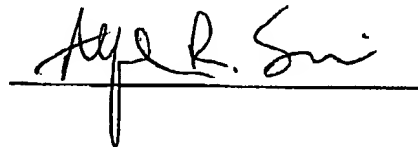
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I have further reviewed the patent of Tesvich and Japanese application as they relate to Claims 3, 4 and 7. I disagree with the examiner in his assessment of the differences between Claims 3, 4, and 7 of Mr. Voisin's application and the combined disclosure of the Japanese application and Tesvich's patent. It is my belief that it would not have been obvious to a person familiar with seafood industry to pressurize seafood at 20,000 p.s.i. and 80,000 p.s.i., without application of heat, without causing damage to shellfish, for a period of time of between 1 and 15 minutes in order to destroy bacteria in raw molluscan shellfish after having reviewed JP 4356156A and Tesvich. The mere fact that Tesvich suggests banding and refrigeration of seafood after "mild heat treatment" does not change the result - neither JP 4356156A nor Tesvich, singularly or combined together, suggest, make inherent or obvious what Mr. Voisin's claims 3, 4, and 7 teach.

I submit that Mr. Voisin's invention is unique and novel in the industry; it provided a viable solution to a long-existing problem. Mr. Voisin achieved success where many others before him failed. It is for this reason that this inventor received acclaim from other seafood processors, who gave him "Processor of the Year" award.
Further declarant saeyth not.

Date: _____

9/24/03



OCT-03-2003 FRI 03:49 PM BON SECOUR FISHERIES
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MOTIVATIT SEAFOODP. 02
002**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Ernest A. Voisin

Serial No.: 09/121,725

Examiner Drew Becker

Filed: July 24, 1998

Group Art Unit 1761

For: A Process of Elimination of Bacteria in
Shellfish, of Shucking Shellfish and
an Apparatus Therefor

DECLARATION

I, Christopher Lee Nelson, declare and say:

That I am a citizen of the United States of America and I reside at 12582 Oak Tree Drive, Magnolia Springs, AL 36555. I began my work in the Oyster industry in 1989 and have been active in this field ever since. I am totally experienced with oyster biology, microbiology, and industry practice.

I am an active member of the National Fisheries Institute, Molluscan Shellfish Institute, National Shellfisheries Association, Southeastern Fisheries Association, Interstate Shellfish Sanitation Conference, Gulf Oyster Industry Council, Gulf States Marine Fisheries Commission, Alabama Seafood Association, South Baldwin Chamber of Commerce, and the Louisiana Oyster Dealers and Growers Association.

I am intimately familiar with the problems faced by the seafood industry and technical solutions offered by numerous individuals and companies.

I am aware that the industry has been actively engaged in finding methods to eliminate naturally occurring marine bacteria, such as *Vibrio vulnificus* and others from seafood.

I have reviewed the above-identified application of Mr. Ernest A. Voisin, the prosecution history of the application, Japanese application identified as JP 4356156A, Cheffel [Effects on high hydrostatic pressure on food constituents: an overview] (page 203, heading 1.2), and patent No. 5,773,064 (Tevich).

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EXHIBIT

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OCT-03-2003 FRI 03:50 PM BON SECOUR FISHERIES
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003

translate, suggest, imply or make inherent the teachings of Claims 6 and 27 of Mr. Voisin's application.

I have also reviewed Cheftel's reference and disagree with the examiner's assessment of the application of that reference to a real-life problem. Cheftel, while theorizing on the possibility of using high pressure in treating cheeses, minced meat and other food products (note the words "provisional and tentative" at the top of the page) also suggests using high pressure in gelation of muscle protein (paragraph 2.1). To me it suggests that Cheftel did not appreciate the danger of indiscriminately using high pressure in oysters and other delicate seafood items if one does not wish to cause irreversible damage of the product. Therefore, it would not have occurred to me to read the Japanese application or Cheftel's page, singularly or in combination, as a guiding manual or even a suggestion for elimination of *Vibrio vulnificus* in molluscan shellfish. I submit that it is not inherent in the Japanese reference and is not recognized inherent by me, based on my experience and knowledge of seafood processing, that the method steps of the Japanese application would result in elimination of bacteria in molluscan shellfish. I have reached the same conclusion after considering Cheftel's paper.

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Further declarant sayth not.

Date:

10/02/03